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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,832	12/28/2000	Henry Hirschberg	Q041	8673

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EXAMINER

SHAY, DAVID M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,832

Applicant(s)

Herschberg

CC

Examiner

J. Shoy

Group Art Unit

3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE — 3 — MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on April 24, 2004
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 4, 6-11, 15-17, 19, 21-34, 37 & 40 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 4, 6-11, 15-17, 19, 21-34, 37 & 40 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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Claims 1, 2, 4, 6-11, 15, 16, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee. Dietrich et al teaches a device as claimed except for the seal at both ends of the lumen; the transparent plug; the seal sealing membrane; and the laser which allows the patient to move freely. Chen et al teach an indwelling PDT device including multiple lumens, which can be sealed at both ends, a plug and a valve, and irradiation over long period of time. Lee teaches the desirability of employing self sealing membranes and shows a funnel-shaped opening. It would have been obvious to employ the self sealing membranes of Lee and the plugs claimed since these would enable the fluid to be retained in the balloon more easily and prevent the incursion of blood or other fluids and to provide low dosage PDT over a longer period of time, since this is more effective against the diseased tissue, as taught by Chen et al, or alternatively to form the spherical radiator of Chen et al as a balloon, since this enables more even illumination in the event the cavity is larger than the radiator, since the balloon can be inflated and would further allow less traumatic removal and insertion of the device, since the balloon can be deflated and in either case to provide a funnel shaped entrance, as shown by Lee since this would tend to guide the inserted device into the passage, which is notorious in the art, thus producing a device such as claimed.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee as applied to claims 1, 2, 4, 6-11, 15, 16, 19, and 21 are above, and further in view of Hayman et al. Hayman et al teach the desirability of combining PDT and radiation treatment. It would have been obvious to the artisan of ordinary skill to employ a radioactive wire, since this a useful adjunct to PDT, as taught by Hayman et al thus producing a device such as claimed.

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Claims 22-26, 28-31, 33, 34, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee. The teachings of Dietrich et al, Lee, and Chen et al are as set forth above, and additionally the total implantation of the irradiator and the use of PDT on breast cancer by Chen et al. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings and provide the stated modifications for the reasons set forth above to produce a method such as claimed and to prolong the treatment over the course of months or a year, since some cancers are very difficult to irradiate, thus producing a method such as claimed.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee as applied to claims 22-26, 28-31, 33, 34, 37, and 40 are above, and further in view of Hayman et al. The teachings of Hayman and the motivations for combination thereof are essentially those set forth above. Thus it would have been obvious to the artisan of ordinary skill to combine these old well known teachings to produce a method such as claimed.

Applicant appears to argue that the references have been combined without motivation. Applicant's attention is respectfully invited to the conclusory statement of the rejections wherein motivations are clearly set forth, along with the reasoning behind there motivation.

The device Chen is clearly entirely subcutaneously implantable. It is noted that there is nothing to prevent an optical fiber from being inserted through the means that allows the reservoir to be refilled. As can be seen from the paragraph spanning columns 18 and 19 of Chen there is an unillustrated embodiment wherein an optical fiber is used in the embodiment of figures 2A and 2B. The device of Chen et al in this embodiment provides a means for repeated

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insertions and removal of an optical fiber. It is also respectfully noted that a *prima facie* case of obviousness is established by presenting evidence indicating that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the teachings before him to make the proposed combination or other modification (see *In re Lintner*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972)). The disclosure of each of the reference relied upon is considered for what it fairly teaches one of ordinary skill in the art, including not only the specific teachings (see *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966)), but also the inferences which one of the ordinary skill in the art would reasonably have been expected to draw therefrom (see *In re Preda*, 401 F.2d 825, 159 USPQ 342 (CCPA 1986)). Finally, one of ordinary skill in the art is presumed to possess a reasonable level of skill in that art, and not a lack thereof (see *In re Sovish*, 769 F.2d 738, 226 USPQ 771 (Fed. Cir. 1985)).

Applicant's arguments filed April 26, 2004 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

This is a Request for Continued Examination of applicant's earlier Application No. 09/750,832. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

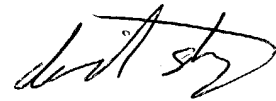
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

Shay/DI

July 1, 2004



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330